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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/784,607

02/23/2004

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EXAMINER

DEMILLE, DANTON D

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/784,607	Applicant(s) TORDELLA ET AL.	
	Examiner Danton DeMille	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-20,22,24-26 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-20,22,24-26 and 28-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/18/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

Claims 1, 3-7, 11-13, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Rotta (US 3,862,629) or Lee et al. (US 3,826,249) in view of either Islava (US 6,719,711) or Shah et al. (US 6,984,215).

Both Rotta and Lee teach a sleeve configured for disposal about a limb that can include a plurality of portions that can define a plurality of expandable sub chambers within each portion. A pressurized fluid source is connected to each chamber for permitting sequential compression vascular therapy on the limb. The sleeve may be separated to completely remove any portion of the sleeve from another portion of the sleeve in order to leave any desired portion intact for delivery of fluid from said pressurized source.

While Rotta and Lee may not use perforations as the means to separate the different portions from each other however, such is well within the realm of the artisan of ordinary skill. Both Islava and Shah teach using perforations to separate different portions of the sleeve as an obvious equivalent means for doing the same thing. Islava at 42 and Shah shows perforations in figs. 2A and 2B between sections 202a and 202b and at column 3, lines 8-14, “[t]he plurality of inflatable sections may be physically coupled to or physically separated (either partially or fully) from one another.” It would have been obvious to one of ordinary skill in the art to modify either Rotta or Lee to use perforations as taught by either Islava or Shah as an obvious equivalent means for performing the same function.

Claims 8-10, 14-17, 22, 24-26, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Dye (US 5,795,312).

Dye teaches ventilation openings 26a-b and 28a-b and also teaches ventilation channel 42 with ventilation openings therein, column 3, lines 43-48. Dye also teaches a thigh portion.

Regarding claims 8-10, it would have been obvious to one of ordinary skill in the art to further modify either Rotta or Lee to include ventilation openings as taught by Dye to provide ventilation to the patient under the sleeve.

Regarding claims 14-17, it would have been obvious to one of ordinary skill in the art to further modify either Rotta or Lee to include a thigh portion including a reduced width knee opening therein as taught by Dye to provide a more complete sequential compression vascular therapy.

Claims 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Mitchell.

When separating the first portion from the second portion of the sleeve one would have to disconnect the hose to the first portion and still be able to operating the second portion by itself. Mitchell teaches a connector, figure 1, in which the downstream tubular pathways 14, 18 have quick disconnect ports 60 for individually disconnecting the downstream tubular pathways as desired or required. It would have been obvious to one of ordinary skill in the art to further modify Dye to include a coupling means as taught by Mitchell so that one can disconnect the tubular pathway to the first portion of the sleeve and still be able to operate the second portion by itself.

Claims 1, 3-11, 13-20, 22, 24-26, 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dye '312 in view of either Rotta or Lee et al. and Islava or Shah et al and Arkans '244.

Dye teaches a sleeve 10 configured to wrap about a leg and defining a plurality of ventilation openings 44. The sleeve includes a thigh portion including sub-chambers 38e and f, a calf portion including sub-chambers 38c and d and an ankle portion defining sub chambers 38a and b. Dye may not teach the thigh portion being removably connected to the calf portion however, there appears to be no unobviousness to separate different parts from one another in order to accommodate different patients needs. Different patients may not need to include the thigh portion of the inflatable sleeve. Other patients may have trauma or had surgery above the knee and therefore including the thigh portion could possibly cause further injury. Being able to remove the thigh portion would appear to be well within the realm of the artisan of ordinary skill.

Both Rotta and Lee teach a sleeve configured for disposal about a limb that can include a plurality of portions that can define a plurality of expandable sub chambers within each portion. A pressurized fluid source is connected to each chamber for permitting sequential compression vascular therapy on the limb. The sleeve may be separated to completely remove any portion of the sleeve from another portion of the sleeve in order to leave any desired portion intact for delivery of fluid from said pressurized source.

Islava teaches perforations such that "[d]etaching one portion 50 from another portion 60 also enables each portion to form a structure independently from the other" column 4, lines 53-55. Islava suggests each portion can be separated from the other in order to provide the ability to be independent. Islava teaches one conventional way of separating two inflatable sleeves one

from the other using perforations. While Islava may be an inflatable splint the same detachable independent function would still be applicable to compression sleeves such as Dye. Shah also teaches a sleeve that allows for the different sections of sleeve to be completely separated for assembly and disassembly and uses zippers to achieve this function. Shah also teaches a pressurized fluid source using tubing and valve connectors in order to shut off each portion as desired. It would have been obvious to one of ordinary skill in the art to modify Dye to be able to separate different portions of the sleeve as taught by either Rotta or Lee so as to remove different sections when they are not needed and to use perforations as taught by either Islava or Shah as an obvious equivalent alternative means of separating the different portions.

Arkans also teaches a valve connector so that upon disconnection the upstream connector closes off the tubular pathway so that the upstream sleeve can maintain pressure. It would have been obvious to one of ordinary skill in the art to further modify Dye to include a valve connector as taught by Arkans to complete the details of closing off the tubular pathway when removing different portions and maintain proper pressure within the remaining portion.

Regarding claim 16, Dye teaches a slit 26a and b that would inherently provide ventilation.

Regarding claim 17, the compression apparatus would be able to perform the claimed operational method and such intended use appears to be within conventional parameters and an obvious provision.

The method of providing the sleeve, disposing the sleeve about the limb, delivering pressurized fluid and deflating the chambers would be well within the realm of the artisan of ordinary skill and inherent in the operation of the prior art device. Since the different sections

can be separated at any time dependent on practical considerations of intended use, there appears to be no unobviousness to remove one section from another in order to change the operation of the device for the next patient or next session. There appears to be no unobviousness to when the sections are separated in order to accomplish the desired therapy. Poole also teaches being able to remove one section of the sleeve to be able to use the remaining sleeve alone as desired.

Claims 12, 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dye '312 in view of either Rotta or Lee et al. and Islava or Shah et al and Arkans '244 as noted above and further in view of Mitchell.

When separating the first portion from the second portion of the sleeve one would have to disconnect the hose to the first portion and still be able to operating the second portion by itself. Mitchell teaches a connector, figure 1, in which the downstream tubular pathways 14, 18 have quick disconnect ports 60 for individually disconnecting the downstream tubular pathways as desired or required. It would have been obvious to one of ordinary skill in the art to further modify Dye to include a coupling means as taught by Mitchell so that one can disconnect the tubular pathway to the first portion of the sleeve and still be able to operate the second portion by itself.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-20, 22, 24-26 and 28-31 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues that the achievement of the instant invention to provide a sequential compression sleeve which is intentionally designed to be separated into different parts as surprising and unpredictable however, both Rotta and Lee teach the heart of applicant's

invention. There is no unobviousness to the exact way in which they are separated. The prior art teaches being torn apart as taught by Shah or cut apart as taught by Arkans or unzipped by Poole or snapped apart by Lee. They are all obvious equivalent alternative ways of doing the same thing. There is no unobviousness to any one of them. They all of their own well known characteristics.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danton DeMille whose telephone number is (571) 272-4974. The examiner can normally be reached on M-F from 8:30 to 6:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu, can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

17 April 2009

/Danton DeMille/

Danton DeMille
Primary Examiner
Art Unit 3771